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FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS MN 55440-1022

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OFFICE OF PETITIONS

In re Patent No. 7,449,475

Hossain et al.

Issue Date: November 11, 2008

DECISION ON APPLICATION

Application No. 10/520,699 : FOR

Filed: January 7, 2005

Attorney Docket No. 06275-427US1/:

100684-1P US

PATENT TERM ADJUSTMENT

This is in response to the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR 1.705(d)," filed December 19, 2008, requesting that the patent term adjustment determination for the above-identified patent be changed from one hundred thirty-one(131) days to one hundred eighty(180) days. For the reasons set forth herein, the request for reconsideration is being treated as a request that the revised patent term adjustment be corrected from one hundred thirty-one(131)days to one hundred seventy-nine(179) days.

The request for reconsideration is granted to the extent that the determination has been reconsidered; however, the request for reconsideration of patent term adjustment is **DISMISSED** with respect to making any change in the patent adjustment determination under 35 U.S.C. § 154(b) of 131 days.

On November 11, 2008, the above-identified application matured into U.S. Patent No. 7,449,475 with a patent term adjustment of 131 days.

This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 1.705(d).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in <u>Wyeth v. Dudas</u>, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that pursuant to <u>Wyeth</u>, a PTO delay under \$154(b)(1)(A) overlaps with a delay under \$154(b)(1)(B) only if the delays "occur on the same day." Patentees maintain that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR \$1.703(b), of 49 days and the period of adjustment due to examination delay, pursuant to 37 CFR \$1.702(a), of 307 days do not overlap as these periods do not occur on the same day.

Patentees argue that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.702(b), is 49 days. Patentees calculate this 49 day period as beginning on the date that is three years after the commencement of the national stage, January 8, 2008, and ending on February 25, 2008, when the first RCE was filed.

Patentees are informed that their calculation of the Three Year Delay period is incorrect.

The commencement date is 30 months from the priority date claimed in the international application, or earlier. The priority date claimed in the international application is July 8, 2002. Thirty months from that date is January 8, 2005 The period of adjustment under \$1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the national stage commenced and ending on the date a patent was issued, but not including the period beginning on the date on which a RCE was filed and ending on the date the patent was issued. Accordingly, the period of adjustment under § 1.702(b) is 48 days, counting the number of days beginning on January 9, 2008 and ending on February 25, 2008 when the first RCE was filed.

Patentees assert that in addition to the three year delay period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a)(1), of 307 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date the application fulfilled the requirements of 35 U.S.C. 371 in an international application.

Under 37 CFR  $\S$  1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on

the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay. The period of reduction of 176 days for applicant delay is not in dispute. Patentees assert that the total period of Office delay is the sum of the period of Three Years Delay (49 days per patentees' calculation) and the period of Examination Delay (307 days, not in dispute) to the extent that these periods of delay are not overlapping.

Patentees contend that no portion of the period of 14 month examination delay of 307 days (March 9, 2006 to January 8, 2007) overlaps with the Three Year Delay period (January 9, 2008 to February 25, 2008). Accordingly, patentees submit that the total period of Office Delay is 356 days, which is the sum of the period of Three Year Delay (49 days) and the period of Examination Delay (307 days), reduced by the period of overlap (0 days).

As such, patentees assert entitlement to a patent term adjustment of 180 days (49 per patentees' calculation +307 reduced by 0 overlap -176 for applicant delay). Considering that the three-year period is properly calculated as 48 days, not 49 days, patentees assertion of entitlement to a patent term adjustment is considered to be 179 days (48+ 307 reduced by 0 overlap - 176 for applicant delay).

As discussed above, the Office states that the patent was pending 3 years and 48 days after the application's commencement date, with the February 25, 2008 RCE ending calculation of the three year period. The Office agrees that the action detailed above was not taken within the specified time frame, and thus, the entry of period of adjustment of 307 days is correct. At issue is whether patentees should accrue 48 (per Office's calculation of the Three Year Delay Period) days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 307 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that all 48 days overlap. Patentees' interpretation of the period of overlap has been considered and found to be incorrect. Patentees' calculation of the period of

overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b) (2) (A), 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b) (2) (A) as permitting either patent term adjustment under 35 U.S.C. 154(b) (1) (A) (i) - (iv), or patent term adjustment under 35 U.S.C. 154(b) (1) (B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b) (1) (A) (i) - (iv) and 154(b) (1) (B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule, 65 Fed. Reg. 54366 (Sept. 18, 2000). See also Revision of Patent Term

Extension and Patent Term Adjustment Provisions; Final Rule, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C.] [35](b)(1) are reduced as follows: (1) To the extent that

there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718<sup>1</sup>

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the commencement date overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the commencement date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period from the application's commencement date through the date the first request for continued examination (RCE) was filed, February 25, 2008.

307 days of patent term adjustment were accorded prior to the issuance of the patent for the Office failing to respond within a specified time frame during the pendency of the application. The 48 days for Office delay in issuing the patent overlap with the 307 days accorded prior to issuance. Accordingly, at issuance, the Office properly entered no additional days of patent term adjustment for the Office taking in excess of 3 years to issue the patent.

In view thereof, the Office affirms that the correct determination of patent term adjustment at the time of the issuance of the patent is 131 days.

The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106<sup>th</sup> Cong. 1<sup>st</sup> Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999) (daily ed. Nov. 17, 1999).

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

Nancy Johnson

Senior Petitions Attorney

Office of the Deputy Commissioner

for Patent Examination Policy